

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
_____)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

October 10, 2007

The Estate of Brenda J. Moreno (the "Estate" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support the claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mario Moreno, Ms. Moreno's spouse and the representative of Ms. Moreno's estate, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

Brenda J. Moreno, the decedent, died on September 23, 2002, at age forty-five. In December 2003, claimant submitted a Green Form to the Trust signed by the attesting physician, Roger W. Evans, M.D. Dr. Evans attested in Part II of claimant's Green Form that Ms. Moreno had severe mitral regurgitation, an abnormal left atrial dimension, the presence of ACC/AHA Class I indications for surgery to repair or replace the mitral valve but surgery was not performed, and that Ms. Moreno's death resulted

3(...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

from a condition caused by valvular heart disease. Dr. Evans also attested that claimant did not have a rheumatic mitral valve. If accepted, claimant would be entitled to Matrix A-1, Level V benefits in the amount of \$1,219,397.⁴

In July 2004, the Trust forwarded the claim at issue for review by Kevin Stephen Wei, M.D., one of its auditing cardiologists. In audit, Dr. Wei concluded that there was no reasonable medical basis for Dr. Evans' finding that the decedent did not have a rheumatic mitral valve. In the Report of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue,⁵ Dr. Wei noted the following:

The mitral leaflets are thickened, and the posterior mitral leaflet is fixed and immobile. There is doming of the anterior leaflet during diastole. On short axis, there is appearance of a "fish mouth os" with evidence of commissural fusion. All features compatible with rheumatic mitral valve disease. Autopsy report also notes that the mitral leaflets were "markedly thickened with dystrophic calcification", and microscopic exam revealed "marked fibrosis, mitral valve, with fibrosis of the chordae tendineae", also compatible with rheumatic mitral disease.

Under the Settlement Agreement, the absence of a finding of no rheumatic mitral valve requires the payment of reduced Matrix Benefits. See Settlement Agreement

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits for death resulting from a condition caused by valvular heart disease. See Settlement Agreement § IV.B.2.c.(5).

5. The Trust did not obtain a Certification from Dr. Wei, because Dr. Wei resigned as an auditing cardiologist due to a conflict of interest. Claimant, however, elected not to have the claim re-audited despite an opportunity to do so.

§ IV.B.2.d.(2)(c)ii)e). The Trust does not contest that claimant is entitled to Level V Matrix Benefits. Rather, the Trust challenges the claimant's right to a payment on Matrix A-1 instead of payment on Matrix B-1.

Based on Dr. Wei's diagnosis that claimant had a rheumatic valve, the Trust issued a post-audit determination that claimant was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"),⁶ claimant contested this adverse determination. In contest, claimant provided an Affidavit from Gregory K. Kobayashi, M.D., and argued that the Estate was entitled to Matrix A-1 benefits because Dr. Kobayashi, a Board-Certified Pathologist, "examined [Ms. Moreno's] mitral valve tissue during the autopsy and determined that there was no specific evidence of rheumatic valve disease."

The Trust then issued a final post-audit determination, again determining that claimant was entitled only to Matrix B-1, Level V benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

18(c). The Trust thereafter applied to the court for issuance of an Order to show cause why the claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5245 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 4, 2005.⁷ The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that the decedent did not have a rheumatic mitral valve. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order

7. Claimant also submitted a sur-reply. Claimant, however, failed to make the requisite showing of good cause for the submission of this sur-reply. See Audit Rule 29(b). Accordingly, the Special Master denied claimant's request to submit a sur-reply by letter on January 4, 2006.

directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate argues that Matrix A-1, Level V benefits should be paid because Dr. Kobayashi, a Board-Certified Pathologist, examined decedent's mitral valve tissue and did not find any evidence of rheumatic valve disease.⁸ In response, the Trust argues that there is no reasonable medical basis for the attesting physician's representation that Ms. Moreno did not have a rheumatic mitral valve.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for the attesting physician's finding that the decedent did not have a rheumatic mitral valve. The Settlement Agreement provides, in pertinent part, that a claim for benefits may be reduced to Matrix B-1 for a rheumatic mitral valve where there is:

M-Mode and 2-D echocardiographic evidence of rheumatic mitral valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease.

Settlement Agreement § IV.B.2.d.(2)(c)ii)e) (emphasis added).

Here, claimant has satisfied its burden based on the Affidavit of Dr. Kobayashi, who stated that: "I examined [decedent's] mitral

8. Claimant also raises issues as to "inter-reader variability" regarding the issues of ejection fraction, mitral regurgitation, aortic regurgitation and left atrial enlargement. As none of these conditions is at issue in this claim, the court need not address claimant's "inter-reader variability" argument.

valve tissue and determined, within reasonable medical probability, that there was no specific evidence of rheumatic valve disease."⁹

We must apply the Settlement Agreement as written. The Settlement Agreement clearly provides that, notwithstanding that a claimant's echocardiogram may reveal evidence of a rheumatic mitral valve, where, as here, a Board-Certified Pathologist examines the mitral valve tissue and determines that there is no evidence of rheumatic valve disease, a claim is not to be reduced to the B-1 Matrix. As claimant has provided the required determination from a Board-Certified Pathologist, claimant is entitled to Matrix A-1 benefits.

Contrary to the Trust's assertion, Dr. Kobayashi did not "base[] his opinion on [the] fact that his autopsy report does not refer to a rheumatic heart valve" and, as such, Dr. Kobayashi's opinion is not "a mere inference based on the absence of a reference in a report created over two years ago" Rather, as reflected in Dr. Kobayashi's Affidavit, his opinion is

9. Although the Trust notes that claimant did not resubmit Dr. Kobayashi's opinion in its response to the Trust's statement of the case and supporting documentation, Dr. Kobayashi's opinion is properly part of the Show Cause Record because, as conceded by the Trust, claimant submitted Dr. Kobayashi's Affidavit during the contest phase of the audit process. See Audit Rule 18(b). The Trust is required to include, as part of its supporting documentation, the entire Audit File, which, by definition, includes claimant's contest materials. See Audit Rules 1(c), 22. Thus, there was no need for claimant to resubmit the Affidavit of Dr. Kobayashi.

based on an examination of the decedent's mitral valve tissue, as required by the Settlement Agreement.

Similarly, we reject the Trust's assertion that Dr. Kobayashi's opinion should be disregarded because he "failed to examine the left atrial appendage and note the presence or absence of an Aschoff body" and, therefore, "Dr. Kobayashi's autopsy report does not exclude rheumatic heart valve disease."¹⁰ The Settlement Agreement only requires that a Board-Certified Pathologist examine mitral valve tissue, not the "left atrial appendage." See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Further, nothing in the Settlement Agreement requires that an autopsy report exclude rheumatic valve disease.

Finally, to the extent that the Trust's auditing cardiologist relied on claimant's autopsy report in reaching his conclusion, such reliance was misplaced as the Settlement Agreement limits a finding by the Trust of a rheumatic mitral valve solely to a review of the echocardiogram. See Settlement Agreement § IV.B.2.d.(2)(c)ii)e). Under these circumstances, claimant has established a reasonable medical basis for the attesting physician's finding that claimant does not have a rheumatic mitral valve.

For the foregoing reasons, we conclude that claimant has met its burden in proving that there is a reasonable medical basis for its claim and, thus, it is entitled to Matrix A-1,

10. The Trust also did not provide any support from the auditing cardiologist for this assertion.

Level V benefits. We will, therefore, reverse the post-audit determination by the Trust and order that the Estate and decedent's spouse be paid in accordance with the Settlement Agreement.

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AND NOW, on this 10th day of October, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that the Estate of Brenda J. Moreno, and the decedent's spouse, Mario Moreno, are entitled to Matrix A, Level V benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805.

/s/ Harvey Bartle III
C.J.